

K | 03704

MAR 23 2012

Section 2. 510(k) Summary

Manufacture Name:	Zephyr Sleep Technologies Inc.
Contact Name:	Sabina Bruehlmann, PhD
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Title:	Director, Research & Development
Date:	December 17, 2010

Device Proprietary Name:	Remotely Controlled Mandibular Positioner, RCMP
Device Common or Usual Name:	Temporary Sleep Apnea/anti-snoring appliance
Classification Name:	Activator Dental Appliance
Classification Code:	Class II (special controls)
Product Codes:	LRK (anti-snoring device) LQZ (jaw repositioning device)
Regulation Number:	21 CFR 872.5570

Predicate Device

Substantial equivalence is claimed to the EMA-T, Elastic Mandibular Advancement – Titration Appliance (K973884) in terms of intended use, design characteristics and certain technology.

Substantial equivalence is claimed to the DemeTECH Polypropylene Surgical Sutures (K043330) for the patient contacting material.

Substantial equivalence is claimed to the Apnea Guard (K111110) for the cleaning instructions for the disposable titration trays.

Description of the Device

The RCMP appliance is a device used in the clinical setting to identify patients with obstructive sleep apnea that will be successfully treated with an oral appliance. A temporary appliance fits to the patient's teeth and incrementally and reversibly advances the patient's mandible anteriorly with respect to the maxilla while the patient is under full polysomnographic monitoring. The repositioning of the mandible pulls the tongue forward and increases the patient's airspace, thereby decreasing upper airway obstruction. Such obstruction can be a causative factor in obstructive sleep apnea and snoring. The RCMP is used in the clinical setting by a technician to advance the mandible until the polysomnographic data indicates removal of the obstruction. The device is used to recommend a target mandibular position that will reduce obstruction of airflow in patients determined to be suitable for oral appliance therapy.

The RCMP appliance consists of upper and lower disposable dental titration trays that are used to hold onto the teeth by means of a quick-set retention material. The trays attach to a mandibular positioner that retracts and extends a rod to adjust the tray positioning by means of a small force linear actuator. By extending the linear actuator rod attached to the upper tray, the RCMP pushes on the upper teeth and pulls on the lower teeth, thus displacing the jaw. RCMP software interacts with the polysomnographic computer and allows the technician to control fine adjustments of the relative position of the mandible.

Intended Use/Indications for Use

Overnight use of a temporary oral appliance to determine in which patients with obstructive sleep apnea mandibular advancement by an oral appliance will reduce obstruction of airflow and thereby to identify patients suitable for oral appliance therapy. The device is also used to recommend a target mandibular position that will reduce obstruction of airflow in patients determined to be suitable for oral appliance therapy.

Patient Population

The RCMP is intended to be used on adult patients that have been previously diagnosed with obstructive sleep apnea upon referral from their physician. It is not intended for use on patients with central sleep apnea, severe respiratory disorders, loose teeth or advanced periodontal disease, or under 18 years of age.

Technological Characteristics

The RCMP appliance is used in a clinical setting under full polysomnographic cardio-respiratory monitoring to identify patients with obstructive sleep apnea that will be successfully treated with an oral appliance. The technician monitors the respiratory air flow and the oxyhemoglobin saturation of the patient during an apnea and titrates the position of the mandible to reestablish normal flow. The final assessment and recommendation for treatment by an oral appliance is completed by a physician who reviews the positioning data and associated cardio-respiratory reaction.

The oral appliances consist of single patient use dental titration trays that are individually customized to fit uniquely into the patient's mouth. The titration trays are connected such that the jaw is held in a fixed occlusal bite plane that allows movement in the anterior-posterior direction. The trays are inserted by the patient on the night of the study under the guidance and supervision of a trained technician.

The oral appliances are connected to a reusable mandibular positioner consisting of a linear actuator, a controller and custom software. Movement of the positioner is controlled by a technician through a software interface.

Substantial Equivalence Comparison

The Remote Controlled Mandibular Positioner (RCMP), is substantially equivalent to the Elastic Mandibular Advancement Titration appliance, EMA-T, (K-973884) manufactured by Frantz Design Inc. The devices have the same intended use, patient population, conditions and environment of use. Note the stated intended use of the RCMP has been modified from that of the predicate for clarity and additional detail. The following table compares the technology and design of the two devices.

Technological Feature	Subject Device RCMP	Predicate (K973884) EMA-T
Titration Trays		
Appliance retention by U-shaped trays filled with impression material	Yes	Yes
Relative displacement visible via a scale on mounting bracket	Yes, and on software	Yes
Jaw constrained to move in the anterior-posterior direction	Yes	Yes
Tray Materials	Moplen HP600N polypropylene ** predicate (K043330)	Spectar (PETG) copolyester
Impression Material, polysiloxane	Yes	Yes
Single patient use	Yes	Yes
Mandibular Positioner		
Repositioning controlled by a trained technician based on readings from a polysomnogram	Yes	Yes
The dental trays are repositioned by	a mandibular positioner consisting of a linear actuator, a controller and custom software.	a technician using their own force to adjust the mandible
The force to the teeth is related to the distance of mandibular protrusion and is exerted on the teeth by the impression material	Yes	Yes

Technological Feature	Subject Device RCMP	Predicate (K973884) EMA-T
The maximum possible force applied is....	restricted by the motor capacity of 2.45 +/- 0.50 kgf	unknown and variable by technician
The protrusive step size is....	is set by the technician, between 0.2 to 2 mm.	is held by a peg in holes at 3mm spacings.
Therapeutic feedback during the repositioning is ...	immediate, the technician observes the response during the repositioning	delayed, as the technician needs to return to the control room
The adjusted position is held by....	the linear actuator; is measured by the software	the insertion of the peg in the hole on the mounting bracket
The observation and recording of mandibular position is made by	a technician using software, with the ability to verify against the scale. No writing or transcribing is required.	a technician
The data is reviewed and the diagnosis is made by a physician	Yes	Yes
Usage	The titration trays are single patient use, and the mandibular positioner is reusable.	None, the trays are a single use design
Source of energy	Electrically powered	No energy source, human exertion

Substantial Equivalence Discussion

The technological differences are directed towards increasing the effectiveness while maintaining the safety of the device. The RCMP was subjected to non-clinical testing and clinical validation to demonstrate its safe and effective performance. The primary technological differences are as follows:

1. The RCMP adjusts the mandible in fine increments (0.2mm) by a remotely controlled linear actuator while the technician observes the immediate cardio-respiratory response in the desired stage of sleep. In contrast, with the EMA-T, the mandible is manually advanced by the technician in set 3 mm increments and results in the patient being continually aroused from their sleep. Clinical testing performed demonstrating safety and effectiveness.
2. The RCMP device is controlled through a software interface. Bench testing and clinical testing performed.

3. The RCMP device includes a linear actuator, a controller, custom software and an electrical energy source. Electrical Safety and Electromagnetic Compatibility testing was performed in accordance with IEC 60601-1 and 60601-1-2.
4. The RCMP mandibular positioner is reusable while the EMA-T has no reusable component. Cleaning and disinfection validation was performed.

Substantial equivalence is claimed to the DemeTECH Polypropylene Surgical Sutures (K043330) for the material of the titration trays which is in contact with the patient. The predicate is inserted into tissue and held for more than 24 hours. In contrast, the trays are placed in contact with mucosal tissue for less than 24 hours.

Substantial equivalence is claimed to the Apnea Guard (K111110) for the cleaning instructions for the disposable titration trays. The RCMP and the Apnea Guard have a similar tray construction and impression material fill. Both devices are fit by a dentist and then provided to the patient for a subsequent use.

Performance Testing

Bench Testing included:

- Patient fit, performance and usability of the titration trays
- Impression material retention testing
- Function of the mandibular positioner including performance of the actuator rod, and enclosure seals for adherence to the specifications
- Mandibular Positioner performance accuracy, including conformance between the software commands and readings and the device behaviour under load conditions
- Software specification and performance evaluation
- Validation of the cleaning and disinfection instructions
- Electrical safety and electromagnetic compatibility testing performed in accordance with IEC 60601-1 and 60601-1-2.
- Cleaning and disinfection validation of the reusable mandibular positioner

Conclusion: The bench tests demonstrated that the RCMP device meets the design requirements, and the device does not raise any new safety or efficacy issues in comparison to the predicate.

Clinical Testing:

A 66 patient clinical study was completed to demonstrate that using prospectively determined criteria, the RCMP test can accurately select favourable candidates for oral appliance therapy. The study also demonstrated that the RCMP test can recommend a therapeutically effective target protrusive distance for the therapy. The study was performed on patients with sleep apnea (RDI >10 in a baseline study) that were recruited from a sleep centre and dentist. The strengths of the study include the following: prospectively determined criterion for inclusion, interpretation and therapeutic success; blinded interpreter and therapist; broad range of patient characteristics; and, appropriate recruitment sources (sleep center and dentist).

The validation study provides evidence that the RCMP test, when implemented in a polysomnographic setting by a trained sleep technician, is safe. As well, the dental titration procedure and approach was intuitively understandable and user friendly to both the technician and the sleep expert; and was shown to be comfortable for the patient. The study included a detailed arousal analysis that demonstrated that the RCMP test does not wake the patient and therefore the titration can be completed during REM sleep.

Conclusion: The clinical study demonstrated that the RCMP is at least as safe and effective as the predicate device at selecting candidates for oral appliance therapy.

Conclusion

Based on the information provided in this 510(k) premarket notification, the RCMP is substantially equivalent in terms of safety and effectiveness to the predicate device identified above.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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MAR 23 2012

Re: K103704

Trade/Device Name: RCMP, Remotely Controlled Mandibular Positioner
Regulation Number: 21 CFR 872.5570

Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for
Snoring and Obstructive Sleep Apnea

Regulatory Class: II

Product Code: LRK

Dated: March 17, 2012

Received: March 19, 2012

Dear Dr. Bruchlmann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

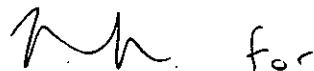
Page 2 – Dr. Bruchmann

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 1. Indications for Use Statement

510(k) Number: K103704

Device Name: RCMP, Remotely Controlled Mandibular Positioner

Intended Use:

Overnight use of a temporary oral appliance to determine in which patients with obstructive sleep apnea mandibular advancement by an oral appliance will reduce obstruction of airflow and thereby to identify patients suitable for oral appliance therapy. The device is also used to recommend a target mandibular position that will reduce obstruction of airflow in patients determined to be suitable for oral appliance therapy.

Prescription Use X

And/Or

Over the Counter Use _____

(21 CFR Part 801 Subpart D)

(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



Division Sign-Off
Office of Device Evaluation

510(k) _____



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K103704